REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The amendment to the claims is editorial in nature and/or further defines what the applicant regards as the invention. Full support for the amendment can be found throughout the present application and the claims as originally filed. In particular, the HLB values of the nonionic surfactants are described, for example, at page 10, lines 19 - 26 and at page 11, lines 17 - 21. The sets of reagents are supported by the present specification as a whole, which clearly describes groups or sets of reagents, such as the first reagent and the second reagent (for example, in the examples at pages 16 - 25). Likewise the particular method steps of claims 34 and 35 are supported throughout the detailed description and the examples. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Objection to the Title

At page 6 of the Office Action, the Examiner requires a more descriptive title. In response, the title is amended as "Reagent Set for Detecting Cholesterol in a High Density Lipoprotein or Low Density Lipoprotein."

Rejection of claims 34 - 35 under 35 U.S.C. §101

At page 2 of the Office Action, the Examiner rejected claims 34 - 35 under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter, on the alleged grounds that the claims recite only the steps of providing a kit and utilizing the kit to assay a lipoprotein fraction. The Examiner alleges that the use of something is not statutory subject matter. For the following

reasons, this rejection is respectfully traversed.

The original claims satisfied 35 U.S.C. § 101. However, to assist the Examiner, claims 34 and 35 are amended herein to provide method steps regarding conducting the assay. Accordingly, amended claims 34 and 35 are directed to a method having well-defined method steps and therefore further constitute statutory subject matter. Therefore, this rejection should be withdrawn.

Rejection of claims 14 - 35 under 35 U.S.C. § 112, first and second paragraphs

At page 5 of the Office Action, the Examiner rejected claims 14 - 35 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleged that the claims are directed to a kit or a method of employing a kit, but that the specification as originally filed does not disclose a kit. For the following reasons, this rejection is traversed.

Reagent kits would be understood by one skilled in the art. This is sufficient for purposes of written description. To assist the Examiner, claims 14 - 35 are amended herein to be directed to a reagent set, instead of a reagent kit. It is respectfully submitted that a reagent set is supported by the present specification, which clearly describes groups or sets of reagents, such as the first reagent and the second reagent (as in the Examples on pages 16 - 25). Therefore, the rejection should be withdrawn.

Also, beginning at page 5 of the Office Action, the Examiner rejected claims 14 - 35 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, at page 6 of the Office Action, the Examiner alleged that the claims are directed to a kit, but do not contain kit limitations, and that it is unclear in claim 14 if the two reagents are combined or separate. For the following reasons, this rejection is respectfully traversed.

As discussed above, claims 14 - 35 are amended herein to be directed to a reagent set. For purposes of clarity, that is, for determining the metes and bounds of the claimed invention, it is respectfully submitted that this is sufficient to describe the invention and that it is not necessary to specify whether the reagents are physically combined or separate. Therefore, this rejection should be withdrawn.

Also at page 6 of the Office Action, the Examiner further alleged that it is unclear in the preamble of claim 14 as to whether detecting cholesterol or detecting HDL is intended. For the following reasons, this rejection is respectfully traversed.

In particular, persons skilled in the art would clearly understand that claim 14 is directed to reagents for detecting cholesterol in an HDL fraction. Therefore, this rejection should be withdrawn.

Also at page 6 of the Office Action, the Examiner further alleged that the term "ion strength increasing compound" is unclear. For the following reasons, this rejection is respectfully traversed.

In particular, persons skilled in the art would clearly understand that the term "ion strength increasing compound" refers to any compound that increases an ion concentration in a solution.

Also at page 6 of the Office Action, the Examiner alleged that the term "reacting cholesterol" does not state with what is reacted. For the following reasons, this rejection is respectfully traversed.

Claim 14 is amended herein to replace the phrase "first enzyme reacting the cholesterol in the high-density lipoprotein" with the phrase "first enzyme that reacts the cholesterol in the high-density lipoprotein," thereby clarifying that the cholesterol reacts.

Also at page 6 of the Office Action, the Examiner alleged that the term "or more" in claim 17 is indefinite because it allegedly reads on infinity. For the following reasons, this rejection is respectfully traversed.

Claim 17 is amended for clarity to change "the hydrazine of 30mM or more" to "the hydrazine at a concentration of 30mM or more." Moreover, there is nothing indefinite about a limitation containing "or more," since the meaning of this term would be clear to persons skilled in the art. For instance, a quick search of the U.S. patent web site shows that over 400,000 issued patents contain claims that use the term "or more." If the Examiner's logic were adopted, all of the patent claims would be invalid for reading on infinity. Therefore, the rejection should be withdrawn.

Also at page 6 of the Office Action, the Examiner alleged that the term "the oxide," used multiple times in claim 21, lacks antecedent basis. For the following reasons, this rejection is respectfully traversed.

Claims 21 and 33 are amended to changing "the oxide" to "an oxide." Therefore, this rejection should be withdrawn.

Rejections of claims 14 - 22 and 26 - 33 under 35 U.S.C. § 103(a) as obvious over Kokusai

At page 3 of the Office Action, the Examiner rejected claims 14 - 22 and 26 - 33 under 35 U.S.C. § 103(a) as obvious over Kokusai (JP 5-176797) entitled "Determination of Cholesterol for Clinical Examination Over Wide pH Range." The Examiner alleged that Kokusai (JP 5-176797) teaches determining cholesterol with a first reagent containing cholesterol esterase, NAD+, Triton X-100 and 50mM hydrazine, and a second reagent containing cholesterol dehydrogenase and Triton X-100. The Examiner acknowledged that Kokusai does not teach a kit

and does not teach the source of the enzymes. However, the Examiner took the position that it would have been obvious to employ the reagents of Kokusai in a kit. Further, the Examiner alleged that all of the claimed enzymes are commercially available and that no novelty is seen in the enzymes or their sources. For the following reasons, this rejection is respectfully traversed.

At the outset, it should be noted that Kokusai does not disclose a reagent set specifically for measuring cholesterol in high-density lipoprotein as recited in the present independent claim 14 or a reagent set specifically for measuring cholesterol in low-density lipoprotein as recited in present independent claim 22. Regarding the specific contents of the claimed reagent sets, Kokusai does not teach or suggest a nonionic surfactant having an HLB value of 16 or more as required by claims 14 and 22. Moreover, regarding claim 14, Kokusai does not teach or suggest a second reagent containing an enzyme that corresponds to the first enzyme contained in the second reagent of claim 14. Moreover, regarding claim 22, Kokusai does not teach or suggest a first reagent containing the nonionic surfactant and cholesterol dehydrogenase or CDH (the second enzyme), which are contained in the first reagent of claim 22. Therefore, this rejection should be withdrawn.

Rejection of claims 23 - 25 under 35 U.S.C. § 103(a) as obvious over Kokusai

At page 4 of the Office Action, the Examiner rejected claims 23 - 25 under 35 U.S.C. § 103(a) as obvious over Kokusai (JP 5-176797) and further in view of alleged Applicant's admissions in the specification. The Examiner acknowledged that Kokusai does not disclose a third enzyme that reacts with the LDL. The Examiner noted that the specification of the present application teaches on page 13, that the free cholesterol in the LDL, VLDL and chylomicron may be preliminarily reacted with COD or CDH to convert into cholestenone hydrazone in the

presence of hydrazine to make a non-substrate state for the time of assaying HDL. The Examiner noted that the specification states that the technology for converting the free cholesterol into a non-substrate is well known and taught in Kokusai. The Examiner takes the position that it would have been obvious to use a third enzyme to remove interfering substances with the teachings of Kokusai because the reagents taught by Kokusai would inherently react with different forms of cholesterol in a selective fashion and that to remove interferents prior to performing an assay is well known. For the following reasons, this rejection is respectfully traversed.

As discussed above, independent claim 22, from which claims 23 - 25 depend, is not obvious over Kokusai. Moreover, as noted by the Examiner, Kokusai does not describe a third enzyme. In particular, Kokusai does not disclose a third enzyme that reacts with the cholesterol in low-density lipoprotein. Moreover, the Examiner is attempting to use the teachings of the present specification to support the prior art rejection, which is improper. The teachings of the present invention are not admitted by applicants as prior art. The MPEP clearly instructs examiners to not rely on the invention being examined for support of a rejection. Therefore, this rejection should be withdrawn.

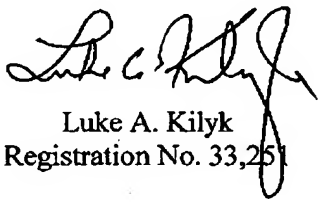
CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to

said Deposit Account.

Respectfully submitted,



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